

WHAT IS CLAIMED IS:

1                    1.        A method for the volumetric distribution of a pharmaceutical agent in  
2 the tissue of a living vertebrate host, said method comprising:

3                    positioning a needle through the wall of a target blood vessel so that an  
4 aperture of the needle is positioned beyond an external elastic lamina (EEL) of the wall by a  
5 distance not exceeding 5 mm; and

6                    delivering an amount of the pharmaceutical agent from the aperture so that the  
7 agent distributes both longitudinally and radially from the injection site.

1                    2.        A method as set in claim 1, wherein the agent distributes longitudinally  
2 along the blood vessel over a distance of at least 1 cm and radially by a distance of at least 1  
3 cm or within a time period no greater than 60 minutes.

1                    3.        A method as in claim 2, wherein the concentrations of agent at all  
2 locations spaced at least 2 cm from the delivery site are at least 10% of the concentration at  
3 the delivery site.

1                    4.        A method as in claim 1, wherein the agent distributes via the lymphatic  
2 system surrounding the target.

1                    5.        A method as in claim 1, wherein the aperture of the needle is  
2 positioned at a distance less than 5 mm beyond the EEL .

1                    6.        A method as in claim 5, wherein pharmaceutical agent comprises a  
2 small molecule drug, a protein, or a gene.

1                    7.        A method as in claim 6, wherein the agent has a maximum dimension  
2 of 200 nm or below.

1                    8.        A method as in claim 1, wherein the blood vessel is a coronary blood  
2 vessel.

1                    9.        A method as in claim 6 , wherein the coronary blood vessel is an  
2 artery.

- 1                    10.    A method as in claim 7, wherein the coronary artery is at risk of  
2    hyperplasia.
- 1                    11.    A method as in claim 7, wherein the coronary artery has regions of  
2    vulnerable plaque.
- 1                    12.    A method as in claim 1, wherein the patient is suffering from  
2    congestive heart failure or a cardiac arrhythmia.
- 1                    13.    A method as in claim 1, wherein the blood vessel is a cerebral blood  
2    vessel and the tissue is in the brain of the host.
- 1                    14.    A method as in claim 1, wherein the blood vessel is a hepatic blood  
2    vessel and the tissue is in the liver of the host.
- 1                    15.    A method as in claim 1, wherein the agent is being delivered to treat a  
2    neoplastic disease in the tissue.
- 1                    16.    A method as in claim 1, further comprising:  
2                    confirming that the aperture is positioned beyond the EEL before delivering  
3    the amount of pharmaceutical agent.
- 1                    17.    An improved method for injecting a pharmaceutical agent into the  
2    tissue of a living host using a needle positioned from a lumen of a blood vessel, wherein the  
3    improvement comprises positioning the needle outwardly from the blood vessel lumen and  
4    confirming that a delivery aperture of the needle has penetrated into tissue beyond an external  
5    elastic lamina (EEL) of the blood vessel before injecting the pharmaceutical agent.
- 1                    18.    An improved method as in claim 17, wherein confirming comprises  
2    injecting contrast media through the needle aperture and observing distribution of the media.
- 1                    19.    An improved method as in claim 17, wherein confirming comprises  
2    monitoring injection pressure.
- 1                    20.    An improved method as in claim 17, wherein confirming comprises  
2    monitoring temperature near the delivery aperture.

1                   21.     An improved method as in claim 17, wherein confirming comprises  
2 monitoring pH near the delivery aperture.

1                   22.     An improved method as in claim 17, wherein confirming comprises  
2 monitoring electrical impedance near the delivery aperture.

1                   23.     An improved method as in claim 17, wherein confirming comprises  
2 monitoring insertion force while positioning the needle through the EEL.

1                   24.     A catheter comprising:  
2 a catheter body;  
3 a needle having an aperture and being deployable from the catheter body; and  
4 means coupled to the needle for detecting when the aperture of the needle has  
5 advanced beyond the external elastic lamina of the blood vessel.

1                   25.     A catheter as in claim 24, wherein the detecting means comprises a  
2 temperature sensor attached to the needle near the aperture.

1                   26.     A catheter as in claim 24, wherein the detecting means comprises an  
2 electrical impedance sensor attached to the needle near the aperture.

1                   27.     A catheter as in claim 24, wherein the detecting means comprises a pH  
2 sensor attached to the needle near the aperture.

1                   28.     A catheter as in claim 24, wherein the detecting means comprises an  
2 insertion force sensor coupled to the needle.

1                   29.     A kit for delivering a pharmaceutical agent to a patient suffering from  
2 or at risk of vascular disease, said kit comprising:  
3 a catheter having a needle which can be advanced from a blood vessel lumen  
4 through a wall of the blood vessel to position an aperture of the needle beyond an external  
5 elastic lamina (EEL) of the wall by a distance not exceeding 5 mm; and  
6 instructions for use setting forth a method comprising:  
7 positioning the needle through the wall of the target blood vessel so that the  
8 aperture of the needle is positioned beyond the external elastic lamina (EEL) of the wall by a  
9 distance not exceeding 5 mm; and

- 10                    delivering an amount of the pharmaceutical agent from the aperture so that the
- 11    agent distributes both longitudinally and radially from the injection site.